



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/058,589	04/10/1998	IAN KIMBER	138.41.US01	7637

7590 05/21/2003
FULBRIGHT & JAWORSKI, LLP
1301 MCKINNEY
SUITE 5100
HOUSTON, TX 77010-3095

EXAMINER

WANG, SHENGJUN

ART UNIT	PAPER NUMBER
----------	--------------

1617

DATE MAILED: 05/21/2003

36

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/058,589

Applicant(s)

KIMBER ET AL.

Examiner

Shengjun Wang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-11, 15-18, 21, 23, 24 and 26-29 is/are pending in the application.
- 4a) Of the above claim(s) 11 and 15-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-10, 21, 23, 24, 26-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 31
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The Request for a Continued Examination (RCE) under 37 CFR 1.114 filed on February 10, 2003 based on Application No. 09/058589 is acceptable and a RCE has been established. An action on the RCE follows.

Receipt of applicants' amendments and remarks submitted February 10, 2003 is acknowledged.

1. Applicants' election in the parent application is presumed to carry over to the instant RCE since applicants have not indicated a contrary intention. Therefore, Claims 11 and 15-19 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 11.

Claims Rejection 35 U.S.C. – 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject-matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-10, 21, 23, 24 and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Teng et al. (of record) in view of Britigan (Advances in Experimental Medicine and Biology, Vol. 357, page 143-156, 1994), Morinaga Milk Inc. (JP 07-233086), and De Lacharriere et al. (US Patent 5,658,581).

Art Unit: 1617

1. Teng et al teach a method of treating dermal inflammatory disorder of human comprising the step of administering a pharmaceutically effective amount of lactoferrin product. See, particularly, page 4, lines 21-30.
2. Teng et al. does not teach expressly the treatment of the particular dermal disorder herein or the employment of biological analog or fragments of lactoferrin.

However, Britigan teaches generally that lactoferrin are known to be useful as an anti-inflammatory agent. See, particularly, page 151, the summary and conclusion. Morinaga Milk Inc. teaches that lactoferrin or its derivatives are known to be useful for treating various skin disorders, including allergic dermatitis. See, the abstract. De Lacharriere et al. teach that TNF antagonists, lactoferrin is known to be useful for treating or preventing skin inflammation induced by certain cosmetic or pharmaceutical allergen, See, particularly, the abstract, column 3, line 4 bridging column 4, line 39, and the claims.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ lactoferrin product for treatment dermal disorder, particularly, skin inflammation, including contact dermatitis or psoriasis. A person of ordinary skill in the art would have been motivated to employ lactoferrin product for treatment dermal disorder, particularly, skin inflammation, including contact dermatitis or psoriasis because lactoferrin is well-known to be useful for anti-inflammation, and is further known particularly useful for treatment of skin inflammation, particularly, allergic dermatitis. Regarding the functional limitation in claim 7, i.e., “a local immune response characterized by increased production of TNF- α ” and in claim 21, “a dermal inflammatory response that is characterized by accumulation of dendritic cell in lymph nodes”, note such limitation is not seen

Art Unit: 1617

to render the claimed invention any patentable weight since the ultimate method, e.g., administering lactoferrin to person with dermal disorder such as contact dermatitis, UV-induced inflammation, psoriasis, skin aging or diaper rash, is not further limited by such functional language. Further, a method for treatment of a symptom would have been reasonably expected to be effective for the treatment of the symptom despite the underline etiology that causes the symptom. Finally, the optimization of a result effective parameter, e.g., effective amount of therapeutical agent, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215.

3. Claims 5-10,21, 23, 24 and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Teng et al. (of record) in view of Nuijens et al (of record) and Enk et al.(Proc. Natl. Acad. Sci. USA, Vol 89, pp 1398-1402, provided in IDS of August, 6, 1998), Database WPI AN 95-340208 (IDS October 2, 1998) and Penco et al. (of record), and further in view of Morinaga Milk Inc. (JP 07-233086).

4. Teng et al teach a method of treating dermal inflammatory disorder of human comprising the step of administering a pharmaceutically effective amount of lactoferrin product. See, particularly, page 4, lines 21-30.

5. Teng et al. do not teach expressly the particular inflammatory dermal disorders herein or the employment of biological analog or fragments of lactoferrin.

6. However, Nuijens et al. teach that lactoferrin reduces the production of IL-1beta and TNF alpha and inhibit proliferation. See, particularly, page 287, third paragraph. Enk et al. teach that both IL-1beta and TNFalpha are responsible for promoting inflammatory activity, including the

Art Unit: 1617

allergen-induced inflammatory activity. See, particularly, the abstract. Penco et al. further teach that lactoferrin inhibits the activity of IL-1beta. See, the abstract. Database WPI AN 95-340208 disclose that lactoferrin analog and fragments are known to be similarly useful as lactoferrin in treating dermal disorder. See the abstract.

Therefore it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to use the method of Teng et al. for inhibiting the dermal inflammatory activity of IL-1beta, as manifested as psoriasis or contact dermatitis, or to employ the lactoferrin active biological analog or active fragments in Teng's method. A person of ordinary skill in the art would have been motivated to use the method of Teng et al. for inhibiting the dermal inflammatory activity of IL-1beta or to employ the lactoferrin biological analog or active fragments in Teng's method because lactoferrin is known for reducing the production of IL-1beta and TNF alpha and inhibiting the activity of IL-1beta and the lactoferrin active biological analog or active fragments are known to be similarly useful for treatment of dermal disorder. Regarding claim 21, 23, 24, note the detailed biochemical process related to the symptomology is not seen to render unobviousness to an otherwise old and well-known method. The employment of lactoferrin for treatment of skin inflammatory disorder is old and well known as discussed above. Further, employment of lactoferrin for treating allergen induced inflammatory disorders is particular obvious in further view of Morinaga Milk Inc. Morinaga Milk Inc. teaches that lactoferrin is useful for treating various dermatitis, including allergic dermatitis. Finally, the optimization of a result effective parameter, e.g., effective amount of therapeutical agent, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215.

Art Unit: 1617

Response to the Arguments

Applicants' amendments and remarks submitted February 10, 2003 have been fully considered, but are not persuasive as to the rejections set forth above.


Applicants' arguments that cited references do not teach expressly the usefulness of lactoferrin in treating allergen induced inflammatory are moot in view of the new ground rejections. Particularly, Morinaga Milk Inc. teaches that lactoferrin is useful for treating various dermatitis, including allergic dermatitis. These teaching further confirm the suggestion by other cited references, the anti-inflammatory activity of lactoferrin is not limited to a particular etiology of inflammatory disorders.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Patent Examiner


PATENT EXAMINER
Shengjun Wang
5-16-03